



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/758,775 | 01/16/2004 | Salih J. Wakil | D6374CIP/ D | 6299 |

7590 11/29/2004
Benjamin Aaron Adler, Ph.D., J.D.
Adler & Associates
8011 Candle Lane
Houston, TX 77071

EXAMINER

HAMA, JOANNE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,775

Applicant(s)

WAKIL ET AL.

Examiner

Joanne Hama, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

This Application was filed January 16, 2004. This Application is a Divisional Application of U.S. Patent Application 09/929,575, now issued as Patent No. 6,734,337, which is a Continuation-in-Part of U.S. Patent Application 09/794,109, now issued as Patent No. 6,548,738.

Claims 1-23 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a method of promoting fatty acid oxidation and weight loss in an individual, comprising a step of inhibiting the activity of acetyl-CoA carboxylase, classified in class 514, subclass 1+.
- II. Claims 7-14 and 20-21, drawn to a transgenic mouse, comprising a mutation in an endogenous ACC-2 gene, classified in class 800, subclass 9.
- III. Claim 15, drawn to a method of screening for an inhibitor of acetyl-CoA carboxylase-2, comprising administering potential inhibitors to wild type mice and screening mice which exhibit a phenotype of consuming more calories than a wild type mouse yet accumulating less fat than a wild type mouse, classified in class 514, subclass 1+.
- IV. Claims 16 and 17, drawn to an inhibitor of acetyl-CoA carboxylase-2, in a pharmaceutical composition, classified in class 514, subclass 1+.

Art Unit: 1632

- V. Claim 18, drawn to a method of inhibiting fat accumulation, comprising the step of administering a pharmaceutical composition, classified in class 800, subclass 3.
- VI. Claim 19, drawn to a method of purifying a preparation of acetyl-CoA carboxylase-1, classified in class 435, subclass 183.
- VII. Claims 22 and 23, drawn to a method of screening for agonists and antagonists of ACC-2, using cells derived from a wild type mouse, classified in class 514, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Invention I is to a method of promoting fatty acid oxidation and weight loss in an individual. Invention II is to a transgenic mouse, comprising a mutation in an endogenous ACC-2 gene. Invention I does not depend on Invention II to function and vice versa.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Invention I is a method of promoting fatty acid oxidation and weight loss in and

Art Unit: 1632

individual. Invention III is a method of screening for an inhibitor of acetyl-CoA carboxylase-2. Invention I does not depend on Invention III to function and vice versa.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is a method of promoting fatty acid oxidation and weight loss in and individual. Invention IV is an inhibitor of acetyl-CoA carboxylase-2, in a pharmaceutical composition.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is a method of promoting fatty acid oxidation and weight loss in and individual. Invention V is a method of inhibiting fat accumulation, comprising the step of administering a pharmaceutical composition. Invention I does not depend on Invention V to function and vice versa.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention I is a method of promoting fatty acid oxidation and weight loss in and individual. Invention VI is a method of purifying a preparation of acetyl-CoA carboxylase-1. Invention I does not depend on Invention VI to function and vice versa.

Art Unit: 1632

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Invention I is a method of promoting fatty acid oxidation and weight loss in an individual. Invention VII is a method of screening for agonists and antagonists for ACC-2, using cells derived from a wild type mouse.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is a transgenic mouse. Invention III is a method of screening for an inhibitor of acetyl-CoA carboxylase-2. The use of Invention II does not depend on Invention III to function, and vice versa.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is a transgenic mouse. Invention IV is an inhibitor of ACC-2. The use of Invention II does not depend on Invention IV to function, and vice versa.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is a transgenic mouse. Invention V is a method of inhibiting fat

Art Unit: 1632

accumulation, comprising a step of administering a pharmaceutical composition. The use of Invention I does not depend on Invention IV to function, and vice versa.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is a transgenic mouse. Invention VI is a method of purifying ACC-1. The use of Invention II does not depend on Invention VI to function, and vice versa.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II is a transgenic mouse. Invention VII is a method of screening for agonists and antagonists of ACC-2, using cells derived from wild type mice. Invention I does not depend on Invention VII to function, and vice versa.

Inventions III and IV are related as process of making and product made, but are distinct. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Invention III is a method of identifying inhibitors of ACC-2, using wild type mice as test subjects. Invention IV is an inhibitor of ACC-2, in a pharmaceutical composition. Invention IV does not have to be identified by the method of Invention III. Instead of using mice, cells derived from mice can be used as a screen.

Art Unit: 1632

Invention III has a different mode of operation from Invention IV. Additionally, Invention III and Invention IV use different protocols.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention III is to a method of screening for an inhibitor of ACC-2. Invention V is to a method of inhibiting fat accumulation. Invention III does not depend on Invention V to function, and vice versa.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention III is a method of screening for an inhibitor of ACC-2. Invention VI is to a method of purifying a preparation of ACC-1. Invention III does not depend on Invention VI to function, and vice versa.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention III is a method of screening for an inhibitor of ACC-2. Invention VII is to a method of screening for agonists and antagonists of ACC-2, using mouse cells. Invention III does not depend on Invention VII and vice versa.

Inventions IV and V are distinct, but related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

Art Unit: 1632

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Invention IV is an inhibitor of ACC-2. Invention V is a method of inhibiting fat accumulation, comprising the step of administering a pharmaceutical composition, comprising the inhibitor in Invention IV. Invention IV is not necessarily limited to functioning as an inhibitor of ACC-2. It may have other biological activities. Invention IV has a different mode of operation from Invention V. Additionally, Invention IV and Invention V use different protocols.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention IV is to an inhibitor of ACC-2. Invention VI is to a method of purifying a preparation of ACC-1. Invention IV does not depend on Invention VI to function and vice versa.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention IV is to an inhibitor of ACC-2. Invention VII is to a method of screening for agonists and antagonists of ACC-2, using mouse cells. Invention IV does not depend on Invention VII to function and vice versa.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

Art Unit: 1632

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Invention V is to a method of inhibiting fat accumulation. Invention VI is to a method of purifying ACC-1. Invention V does not depend on Invention VI to function and vice versa.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention V is a method of inhibiting fat accumulation. Invention VII is to a method of screening for agonists and antagonists. Invention V does not depend on Invention VII to function and vice versa.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention VI is to a method of purifying a preparation of ACC-1. Invention VII is to a method of screening for agonists and antagonists of ACC-2, using mouse cells. Invention VI does not depend on Invention VII to function and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and the search for one Invention is not required for the search of another Invention, restriction for examination purposes as indicated is proper.

Art Unit: 1632

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is (571) 272-2911. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

Joe Winters
AU 1632